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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/199,874	11/24/1998	GINO V. SEGRE	00786071005	4165

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EXAMINER

PAK, MICHAEL D

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 05/21/2002

28

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**Application No.  
**09/199,874**Applicant(s)  
**Segre et al.**Examiner  
**Michael Pak**Art Unit  
**1646**

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on Feb 25, 2002.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 40-71 is/are pending in the application.
- 4a) Of the above, claim(s) 41, 44-56, and 58-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40, 42, 43, and 57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 26      6) ☐ Other:

**DETAILED ACTION**

1. Applicant's election without traverse of Group VI, in Paper No. 27 is acknowledged.

Claims 40, 42-43, and 57 belong to group VI which are drawn to method of identifying a compound by binding a human receptor polypeptide with a parathyroid hormone. The examiner had indicated that claims 41 and 52 and 53 were part of Group VI which was made in error. The examiner regrets any inconvenience to the applicant. The SEQ ID NO: 5-13 of claims 41 were derived from rat PTHR. Claims 52 and 53 are drawn to opossum PTHR.

Claims 40-71 are pending and claims 40, 42-43, and 57 are being examined.

**Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 40, and 42-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 40 encompass the term ~~parathyroid hormone receptor~~ which is ambiguous because the it is not clear what is the metes and bounds of the term. The term is not defined in the specification and the claim limitations are drawn to structural limitations which requires an initial structure recited in the claim in order to determine the boundaries of the structural limitation. Claims 42 and 43 are dependent on claim 20.

Claims 42 and 43 recite ~~naturally occurring~~ which is ambiguous because the it is not clear what is the metes and bounds of the term ~~naturally occurring~~. It is not clear when the receptor is naturally occurring or not and what is the naturally occurring receptor since depending on the definition of the term there may be several naturally occurring forms.

3. Claims 40, 42-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims encompass a polypeptide variant PTH receptor which is naturally occurring but not disclosed in the specification nor to one of skilled in the art. The essential feature of the invention is the method of binding using the SEQ ID NO:21 PTH receptor. Claimed polypeptide variants encompass a large genus of receptors which are alleles or variants whose structure has yet to be identified from different species of animal because the structure of the newly identified naturally occurring receptor is not known. One of skilled in the art cannot envision the sequence which has not been identified. *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification.

4. Claims 40, 42-43, and 57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of using the receptor which comprises the structural domain which binds the PTH, does not enable a method of using a PTH receptor which is six amino acid long to any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims encompass a polypeptide fragments and variants of PTH receptor which is six amino acid long. However, the specification does not teach how to use fragments and variants of PTH receptor which does not bind ligands. G-protein binding receptors have a binding domain comprising the hydrophobic pocket created by all seven of the transmembrane region. A fragment of the G-protein binding receptor which is truncated in the middle of the hydrophobic pocket or a fragment which does not allow the proper folding of the hydrophobic pocket would not be expected to function since the ligand could not interact with the pocket necessary for intracellular signal transduction function. Furthermore, the state of the art is such that one skilled in the art cannot predict the outcome of changes to protein structure using the primary amino acid structure as the predictor. Thus, one skilled in the art cannot use the primary amino acid sequence of the PTH receptor alone to predict the tertiary structure of the polypeptide which would be required to determine ligand binding function, and proper folding of PTH receptor polypeptide variant with large number of amino acid substitutions. No working example nor guidance are provided to determine whether a change in the hydrophobic ligand binding pocket for PTH polypeptide fragment or variant could bind a ligand. No working example or guidance is provided to use polypeptide without binding function. Thus, such fragments encompass a genus with a

large number of species which are not functional. In view of the extent and the unpredictability of the experimentation required to practice the invention as claimed, one skilled in the art could not make the invention without undue experimentation.

**Claim Rejections - 35 USC § 102**

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 40, 42-43 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Lindall et al. (US 4,508,828).

Lindall et al. teach the method of identifying a compound which competes with parathyroid hormone and wherein the compound is the peptides PTH analogues (columns 1,2, 9-12). The PTH receptor in human kidney cortical cell culture of Lindall meets the claim limitations because the human PTH receptor in the human cell inherently comprises the part of the amino acid sequences of SEQ ID NO:21 and is processed for loss of N-terminus methionine.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Michael D. Pak*  
Michael D. Pak  
Primary Patent Examiner  
Art Unit 1646  
14 May 2002